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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/829,549
Filing Date: April 10, 2001
Appellant(s): ENGLISH ET AL.

Edwards Hejlek
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 18,2007 appealing from the Office action mailed July 25, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2001/0029024 KODAKEK 10-2001

Gough, K.C., J. "Selection of phage antibodies to surface epitopes of Phytophthora infestans", Journal of Immunological Methods, 228, (1999), pp.97-108.

Petrenko, V. A. " A library of organic landscapes on filamentous phage" Protein Engineering, vol. 9, (1966), pp. 797-801.

Smith, G.P. Libraries of Peptides and Proteins displayed on Filamentous Phage" Methods in Enzymology, vol. 217, pp.228-257, (1993).

6,235,974 QUI 05-2001.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

Claims 1-4, 6-9, 32-34, 37-43, 45-47 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al in view of Kodadek et al and Petrenko et al.

Gough et al discloses at page 98, col. 1 up to page 105 a phage-displayed method for generating antibody from a diverse library of antibodies fused to a vector and panning against the

specific plant fungus, Phytophthora infestans. See further the section under the Materials and Method at page 98 which describes the specific steps of the phage display method. Gough does not disclose a non-Ig peptides as used in the method and a f8-1 peptide library. However, Kodadek et al discloses at paragraph [0009] that antibodies-which are not low molecular weight compounds- are relatively fragile compared to small molecules. These antibodies, using classical method, are tedious and expensive to obtain, particularly in large quantities. Antibodies are not easily rendered cell-permeable.

Petrenko discloses at page 797 up to page 798 the use of f8-1 in phage method to obtain phage peptide that do not only include local functionalities that reside in a single variable peptide and its immediate surroundings but also global functions that inhere in the entire surface landscape.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a small molecular weight compounds as peptides in the method of Gough as taught by Kodadek and Petrenko. The numerous disadvantages in the use of antibodies as taught by Kodadek, above and the advantages taught by Petrenko in the use of peptide would provide the motivation to one having ordinary skill in the art.

Claims 44 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al in view of Kodadek et al and Petrenko as applied to claims 1-4, 6-9, 32-34, 37-43, 45-47 and 49-51 above, and further in view of applicants' disclosure of known prior art.

Gough does not disclose the phage as f88-4. Appellants at page 11, line 28 up to page 12, line 2 of the specification states ".....methods for the production of the f88-4 phage-displayed peptide library have also been previously described..... This library displays 15-amino acid foreign peptides on 150 to 300 copies of major coat protein pVIII. The remainder of the 3900 copies of the pVIII subunits is derived from the wild type pVIII. The phage genome thus bears two pVIII genes encoding two different types of pVIII molecules. One pVIII is the recombinant displaying the foreign 15-mer peptide, while the other is the wild-type pVIII normally present on the phage. Because of the presence of two pVIII genes, the f88 virion consists of a mosaic pattern of wild-type and recombinant pVIII subunits. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ in the method of Gough the known phage f88-4 as disclosed in appellants' disclosure of a known prior art. One would be motivated to use this phage because of the characterizing

properties of this phage e.g., the presence of two genes with a mosaic pattern of wild-type and recombinant p8. This mosaic pattern or landscapes (see Petrenko) include clones exhibiting emergent properties that inhere in the entire surface architecture, not in the peptides by themselves.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al (Jrnl. Of Immunological Methods, 1999) in view of Kodadek et al (US 20010029024) and Petrenko as applied to claims 1-4, 6-9, 32-34, 37-43, 45-47 and 49-51 above, and further in view of Smith (Methods in Enzymology).

Gough and Petrenko, as discussed above, do not disclose a random oligonucleotide of the sequence GCA GNN (NNN)7, as claimed. Petrenko discloses at page 797, col. 2 a random oligonucleotide sequence comprising the sequence GCA GNK(NNK)6 as opposed to the claimed GCA GNN(NNN)7 i.e., a variable NNK as opposed to NNN as claimed. However, Smith at page 243 discloses the two general types of synthetic degenerate oligo libraries. One is the fully degenerate codons (NNN) that encode all 20 amino acids with no bias beyond what is entailed by the unequal degeneracy of the genetic code while doped codons are biased toward one particular amino acid in order to introduce random substitutions into a base peptide sequence. Accordingly, it would

have been obvious to one having ordinary skill in the art at the time the invention was made to use the fully degenerate NNN codon in the method of Gough as taught by Smith. One would be motivated to use the NNN codon since this codon includes all the naturally occurring 20 amino acids with each of the 20 residues equally represented in the library i.e., with no bias to a particular amino acid. Smith teaches that either one of these degenerate oligo libraries (NNN or NNK) can be used to introduce random substitutions into a base peptide sequence.

Claims 35, 36 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al in view of Kodadek et al and Petrenko as applied to claims 1-4, 6-9, 32-34, 37-43, 45-47 and 49-51 above, further in view of Qui (6,235,974).

Gough discloses several Phytophthora species one of which is the claimed Phytophthora infestans but not the other Phytophthora species as recited in e.g., claim 35. However Qui discloses at col. 22, line 50 up to col. 23, line 4 the different species of Phytophthora that are known in the art at the time of the invention. These different species have the same hypersensitive response to elicitor proteins. It would have been obvious to one having ordinary skill in the art to use other phytophthora species in the method of Gough as taught by Qui.

Qui discloses that many different Phytophthora species respond equally to an e.g., elicitor protein. One would be motivated to use a particular Phytophthora species if this is the species present in a plant causing fungi disease and the desire to eradicate its presence in plants.

(10) Response to Argument

Appellants acknowledge that the methods of Gough et al were ***generally effective*** in identifying antibodies that bind to the surface of Phytophthora. But argue that Gough et al admit that their antibodies and others identified to date have had no effect on Phytophthora whatsoever. Appellants nonetheless acknowledge that Gough et al. still promise that other antibodies to surface epitopes of Phytophthora having a pathogenic effect could still be identified:

> The panning of whole pathogens might be expected to yield scFvs that bind to unmodified surface antigens that may be of importance in the infection process. However, preliminary assays, in which sporangia were mixed with soluble MBP-scFv fusion protein and then used to inoculate tomato leaf discs (Niderman et al., 1995), showed no detectable anti-fungal activity for any of the antibodies. Nevertheless, the isolation of other scFvs specifically directed against the native conformation of surface-accessible antigens may well provide new tools to probe and manipulate pathogenicity.

In response, there is nothing in the above-quoted passage of Gough that indicates "the antibodies and others identified to

date" had no effect on Phytophthora. Rather, section discloses that the lack of response is on a preliminary assay in the sporangia of tomato leaf discs.

In this respect, Appellants' attention is drawn to the teachings of Gough in **its entirety**, for example, at page 104:

> ….Affinity-purified MBP-scFv fusion proteins were assayed for binding to mycelial homogenates from a **range of plant pathogenic fungi *(Fig. 8)***. Antibodies g15, s1 and s2 were characterised and all produced similar binding patterns. With the exception of the binding of g15 to P. cactorum, the highest ELISA signals were produced with homogenates of the Phytophthora species: P. infestans mating strains AI and A2, P. citricola. P. cactorum and P. megasperma. For each of the MBP-scFv fusions, a lower signal was obtained with a homogenate of Pythium deliense, the other member the Peronosporales, and even lower signals were obtained with homogenates of the unrelated species Ascochyta pisi. Fusarium culmorium and Aphanomyces euteiches. ***These results indicate that in general the scFvs isolated from the panning and subpanning procedures recognize epitopes that are common to different Phytophthora species…*** (Emphasis added.)

See further, including but not limited to page 101, Figs. 2 and 3 and RESULTS; page 102, Figs. 4 and 5; page 103, Figs. 6 and 7 and at page 102, col. 1, first complete paragraph up to col. 2, first incomplete paragraph.

Appellants argue that the substitution of random peptide libraries for antibody fragment libraries would be unproductive as Gough et al. seek to identify antibodies which can be used in immunological methods, not mere non-immunoglobulin peptides. In general, the single-chain Fv antibodies utilized in the methods

of Gough et al. is far more complex than the simple peptides in the library of claim 1. Single-chain Fv antibodies such as those utilized in the methods of Gough et al. consist of three independent variable regions of amino acids that are constrained in some fashion (e.g., by folding) by the remaining scFv scaffold. Consequently, the three regions can interact with a target in a constrained manner that is complex and difficult to predict. The scFv scaffold itself may also interact with the target in some manner. Stated another way, the active binding portion of the antibody fragment may or may not work by itself upon subsequent isolation, and/or molecular structures and components other than the active binding portion may be responsible for binding epitopes or surface functions on the target independently or in conjunction with the active binding portion. The random peptide libraries of claim 1 have far greater utility since they simply have some level of affinity to cell surface factors on the target fungus, without the additional ancillary protein sequences involved in the complex aspects of antibody structure and form. That is, the selected non-immunoglobulin peptides of Appellants' claimed invention can work outside of or independently from a phage-antibody framework to provide a more direct interaction with its targets.

In reply, most of appellants' arguments above are not commensurate in scope with the claims. The claims do not recite a simple non-Ig peptide. There are no identifying or characterizing features of the non-immunoglobulin(Ig) peptide to designate it as a simple peptide compared to Gough's scfv fragment. The fact is, peptide is a generic name that has been applied variously in the art, possibly including the (poly)peptide fragment, scFv.

Gough at least suggests a peptide (page 98, paragraph bridging col.1 and col. 2):

> The strategy described here for the isolation of antibodies against surface targets employs a phage-displayed single-chain Fv(scFv) library in combination with affinity selection against whole organisms or external soluble components that should result in the selection of antibodies specific for native external epitopes. This rationale has been successfully applied to the selection of **phage-displayed *peptides*** that bind to the surface receptors…" (Emphasis added).

Appellants argue that the examiner's reference to Gough above implies that mere peptides would be inadequate to accomplish the clearly-stated objectives of Gough et al.

In response, whether the objective of Gough is to ultimately find an immunological probe is immaterial. The claimed screening method of identifying a peptide using diverse phage library having affinity to fungus surface is clearly taught by Gough.

Thus, at the time of appellants' invention screening of either peptide or (poly)peptide(scFv fragments) by phage display method is known in the art and had been applied to various peptides in general. (It is of interest to note appellants' REMARKS at page 8 made on 9/8/2003. Appellants state:

> "..in general, the method of claim 1 is applicable to many different fungi, and thus, non-lg peptides that bind to a number of fungi can be identified.."

Appellants state that Kodadek is concerned with the selection of library encoded peptides having affinity to a single, specific, known target peptide, not a surface with a multitude of unknown epitopes such as the surface of a fungus. Kodadek is not contacting his library encoded peptides with anything other than a provided target peptide (e.g., the protease cleavage site of the human insulin-like growth factor to identify binding partners to that particular target.

In response, the preamble of the claim recites a surface of a fungus but does not indicate a multitude of unknown epitopes. Kodadek is employed not for the purpose as argued, as Gough discloses this fungal surface. Kodadek is employed for the purpose or motivation of using a peptide:

> [0036] …an important goal in chemical biology is to be able to obtain specific ligands for any biomolecule of interest. Impressive advances have been made in isolating molecules,

> many of which are antibodies or antibody-derived, that bind proteins and nucleic acid targets with well-defined macromolecular structures. However, the identification of sequence-specific, peptide-binding ligands has been more difficult. In addition, even antibodies have major drawbacks: they are tedious and expensive to generate, difficult to produce in large quantities, are relatively fragile molecules unsuitable for certain field applications, and often bind so tightly that they or their target proteins are damaged upon attempted extraction. Natural peptide-binding proteins or protein domains have been mutagenized to derive species with novel binding specificities (Schneider et al., 1999), but like antibodies, these are globular macromolecules. Thus, though the development of synthetic receptor molecules has seen important advances in the last few years, the field remains in its infancy. ***Therefore, it remains an important goal to develop non-macromolecular species that retain the favorable molecular recognition characteristics of antibodies, but can be identified quickly and easily and synthesized in large amounts.*** (Emphasis added.)

Appellants' statement above regarding the complex nature of scFv would provide the motivation to one having ordinary skill in the art not to use said macromolecular complex antibodies (scFv).

Appellants argue that Kodadek instead of providing motivation clearly indicates that one skilled in the art would actually be guided away from combining the disclosures of Gough et al and Kodadek. Keeping this standard in mind, it is significant that Kodadek refers to the futile attempts to identify peptide complexes using phage display that, in Kodadek's words, not only failed but "failed completely." Kodadek then goes on to describe his genetic selection scheme designed to be an improved method, in and of itself, to overcome

past failures in identifying peptide complexes. It is only after particular, weakly-binding library encoded peptides that bind to the known target peptide are identified by the genetic selection scheme (i.e., on the basis of affinity) that Kodadek coupled them with conventional phage display methods to form a pincer. Thus Kodadek clearly implies (and in some respects states outright) that conventional phage display methods, standing on their own, would not work.

In response, as clearly stated by appellants above, the improved method of Kodadek led to the identification of peptides albeit, the improved method combined phage with the other method. However, the claims do not preclude the presence of other methods combined with phage.

The full text of the reference at page 4, paragraph [0038] states:

> The overall goal of this project was to develop a general method for the discovery of relatively low molecular weight EBMs that can be chemically synthesized (i.e., they are not macromolecules such as antibodies, other types of proteins, or nucleic acids). Thus, the inventor initiated an effort to isolate heteromeric complexes comprised of small peptides, even smaller than leucine zippers that could be employed as EBMs. As stated above, a priori, it was not clear how feasible this endeavor would be. Stable, specific complexes between naturally-occurring peptides of less than 25-30 residues are essentially unknown, although complexes between small peptides and large proteins are very common. This is probably because macromolecular proteins have cavities into which a peptide can insert, thereby shielding many of the interactions from competition by solvent water.

> This kind of shielding is not possible for complexes between small peptides. Additionally, most peptides do not adopt stable secondary or tertiary structures, leading to the expectation that the entropic cost of forming a complex between small peptides would be much higher than binding of a peptide to a structurally well-defined protein. These very reasonable biases have presumably deterred efforts to identify such complexes and to use them in biotechnology applications. This bias was also supported by early efforts of the inventor and his co-workers to accomplish this goal through the use of well-established methods, including the yeast two-hybrid system (Fields and Song, 1989; Yang et al., 1995) and phage display (Burton, 1995). These approaches failed completely. (Emphasis added.)

Attention is further drawn to the disclosure of Kodadek reference at page 14, paragraph [0136], which teaches for screening by phage-display method pincer libraries. Also, at paragraph [0132] and Fig. 7 which describe the biological approach of pincer library by display on the surface of a bacteriophage. Paragraph [0137] up to paragraph [0139] describes the random mutagenesis of the library.

Appellants state that in Petrenko et al the phage displayed library of peptides was panned against a single known target (i.e., not a multitude of unknown targets such as those on the surface of a fungus). The lack of teaching, suggestion, or motivation in Gough et al and Kodadek is not remedied by the disclosure of Petrenko et al. Petrenko et al describe panning phage displayed peptides against, like Kodadek, a single known target seeking to identify phage clones that exhibit "global

properties" across the entire phage surface (e.g., chloroform resistance), irrespective of the particular peptides of the library.

In response, the response under Kodadek above is incorporated here since appellants present the same arguments as above i.e., the used of a single target.

Appellants argue that the rejection of claim 1 is nothing more and nothing less than an impermissible hindsight rejection, using Appellants' disclosure as a template.

In reply, the combined teachings of the cited prior art are not based on hindsight. The phage method of screening a library of peptide is a method commonly employed in the art. Appellants merely applied this known method to fungi surface, which Gough teaches. Thus, there is nothing new or unobvious about the claimed method since the method is already known and a commonly employed screening method in the art.

It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claims 9 and 41-43 (The Group II Claims) Claim 9 is representative of the Group II claims. It depends from claim 1

(or claim 48) and additionally requires that each of the peptides be the same length, the length being 6 to 15 amino acids.

Appellants argue that in contrast to the methods of Gough et al., claim 9 requires the use of peptides that are the same length, the length being 6 to 15 amino acids, not scFv antibody fragments. The single-chain Fv antibodies utilized in the methods of Gough et al are far more complex than the simple, 6- to 15-met random peptides required by claim 9. While the Office cites no authority regarding the molecular weight of scFv antibodies, it is the Appellants' understanding that such scFv antibodies generally have a molecular weight of at least about 24,000, with 29,000 to 30,000 being typical. Based on a molecular weight of 24,000 and using an average molecular weight of 137 for the 20 possible amino acids, Gough et al's antibody fragments would be about 175 amino acids in length; thus, Gough et al's antibody fragments are, at a minimum, 12 times lonqer than the 6- to 15-mer peptides required by claim 9. Appellants nonetheless recognize that **Kodadek** uses both random peptides (e.g., 6 to 15-mer peptides as required by claim 9).

In reply, the numerous disadvantages cited by appellants above for scFv, would motivate one having ordinary skill in the

art to replace the high molecular weight scFv fragments with peptides of low molecular weight.

Rejection of claims 44 and 49 under 35 U.S.C. 103(a) over Gough et al in view of Kodadek and Petrenko et al, and further in view of Appellants' disclosure of known prior art.

Appellants acknowledge that at the time of Appellants' invention, random peptide libraries in general were known in the art, and included such random peptide libraries as the f8-1 and the f88-4 phage-displayed peptide libraries. Accordingly, Appellants' specification describe some of the features of the f8-1 and the f88-4 phage-displayed peptide libraries that may be used in the Appellants' claimed invention and provides citations for the relevant art describing methods for the production of these phage-displayed peptide libraries. But argue that none of the references cited by the Appellants describe the use of the f8-1 and/or the f88-4 phage-displayed peptide libraries in connection with Phytophthora species, nor do they suggest that such uses could be carried out. Thus, while the f8-1 and the f88-4 phage-displayed peptide libraries and methods for their production were known, it was nonetheless nonobvious to use such phage-displayed peptide libraries to pan against surface exposed epitopes on Phytophthora species. In fact, claim 44 does not even require that the peptide library be expressed on phage.

In reply, Petrenko at page 797, col. 2, Materials and Methods section under A discloses the known vector f8-1, as similarly acknowledged by appellants is known in the art. The combined teachings of the prior art, Gough, which teaches Phytophthora species and Petrenko, which teaches the known phage vector, f8-1 would have led one having ordinary skill in the art to the claimed vector, f8-1.

Rejection of claim 5 under 35 U.S.C. 103(a) over Gouqh et al. in view of Kodadek and Petrenko et al., and further in view of Smith et al.

Appellants state that Smith et al is a review article discussing conventional libraries of peptides and phage-displayed proteins and methods for their production. Smith et al discuss the use of degenerate oligonucleotides and their use in the production of peptide libraries having synthetic degenerate (i.e., random) oligonucleotides as the insert. Appellants recognized that this feature is the nature of the "random" peptide library. Like the f8-1 and the f88-4 phage-displayed peptide libraries, random oligonucleotides and their use in peptide libraries is known in the art. Smith et al, however, provide neither suggestion nor motivation to utilize degenerate oligonucleotides in the methods of Gough et al.

In response, as acknowledged by appellants above, the random nucleotide represented by N is a nature of the random peptide library. Since this random peptide has been known to have successfully identified peptides from this library hence, one having ordinary skill in the art would be motivated to employ said random library. (See Petrenko, at page 797, col. 2, Materials and Methods section under A. Kodadek at page 16, paragraphs [0152]-[0156], especially the references cited therein e.g., Short.) Also, because a random library, which employs all the 20 naturally occurring amino acids would contain a more diverse peptide.

Rejection of claims 35, 36, and 48 under 35 U.S.C. 103(a) over Gough et al. in view of Kodadek and Petrenko et al., and further in view of Qui et al.

Appellants state that Qui et al. is directed to methods for imparting pathogen resistance to plants by applying a hypersensitive response elicitor polypeptide isolated from its corresponding organism to a plant seed. According to Qui et al., the elicitors are polypeptides or proteins that are able to elicit local necrosis (i.e., a hypersensitive response) in plant tissue contacted by the elicitor. The elicitor-mediated hypersensitive response is a widely distributed pathogen defense mechanism known to occur across a ***wide variety of plant species***

in response to bacterial and fungal pathogens. Accordingly, Qui et al. describe that their elicitor polypeptides are "derived from a wide variety of fungal and bacterial pathogens. As examples of bacterial sources for their elicitor polypeptides, Qui et al. mention Erwinia, Pseudomonas, and Xanthomonas species, and as examples of fungal sources for their elicitor polypeptides, Qui et al. mention Phytophthora. Phytophthora parasitica, Phytophthora cryptogea, Phytophthora cinnamomi, Phytophthora capsici, Phytophthora megasperma, and Phytophthora citrophthora are listed as suitable source materials for the elicitor polypeptides. Appellants acknowledge that there are a number of Phytophthora species known in the art, some of which are cited in the Appellants' specification and/or the disclosure of Qui et al. others which are not. Other than naming three of the five Phytophthora species recited in Appellants' claim 48, the Qui et al. reference is non-analogous to the Appellants' invention. Rather than choosing to cite an index of all formal names in the Kingdom Fungi pertaining to Phytophthora, the Office apparently chose Qui et al. Qui et al. do not suggest that any of the numerous source fungi for hypersensitive response elicitor polypeptides would be desirable in the methods of Gough et al. The methods of Gough et al. and Qui et al. are far too disparate for one of skill in the art to combine. In

other words, while Qui et al. recited several exemplary Phytophthora species as sources for their elicitor polypeptides, some of which were included in the Appellants' claim 48, this disclosure would not motivate one skilled in the art to substitute various Phytophthora species in the methods of Gough et al.

In reply, as acknowledged by appellants, one can even use an index of all formal names in the Kingdom fungi pertaining to Phyophthora, even without using Qui, to pick and choose those Phytophthora species that are suitable for the intended purpose. One would reasonably expect to successfully apply across this wide variety of species (see Qui, supra) the claimed method as evident from the results obtained by Gough (Fig. 8).

In conclusion, the combined teachings of the prior art would have led one having ordinary skill in the art to the claimed method. The claims do not present anything new and unexpected from the known use of phage display method for screening a random library of peptides to identify peptide that has an affinity for the fungus surface.

For the above reasons, it is believed that the rejections should be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully submitted,

tdw

May 11, 2007

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